ARK Diagnostics, Inc.

ARK™ *Fentanyl Calibrator*

This ARK Diagnostics, Inc. package insert for the ARK Fentanyl Calibrator must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

CUSTOMER SERVICE

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KEY TO SYMBOLS USED

LOT	Batch code	YYYY-MM-DD	Use by/Expiration date
REF	Catalog Number		Manufacturer
	Consult Instructions for Use	CALIBRATOR	Calibrator
	Temperature limitation	IVD	*In Vitro* Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ *Fentanyl Calibrator*

2 INTENDED USE

The ARK Fentanyl Calibrator is intended for use in calibration of the ARK Fentanyl 0.5 ng/mL Assay.

3 CONTENT

The ARK Fentanyl Negative Calibrator is composed of a non-sterile, processed human urine matrix that is negative for fentanyl. The ARK Fentanyl Cutoff Calibrator is composed of non-sterile, processed human urine containing 0.5 ng/mL of fentanyl.

REF	Product Description		Quantity/Volume
5052-0002-01	**ARK Fentanyl Negative Calibrator** Human urine, stabilizer and sodium azide		Dropper vials
	Negative	0.0 ng/mL	2 X 10 mL

REF	Product Description		Quantity/Volume
5052-0002-02	**ARK Fentanyl Cutoff Calibrator** Fentanyl, human urine, stabilizer and sodium azide		Dropper vials
	Cutoff	0.5 ng/mL	2 X 10 mL

4 STANDARDIZATION

There is no internationally recognized standard for fentanyl. A certified solution of fentanyl is traceable to HPLC. ARK Fentanyl Cutoff Calibrators are prepared by volumetric dilution of this certified solution into non-sterile, processed human urine free of fentanyl.

Calibrators are made with non-sterile, processed human urine free of fentanyl. Donors were non-reactive in tests for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT) and RPR.

5 WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Harmful if swallowed.
- Contains human urine. Handle as potentially infectious.
- Product contains ≤0.09% sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides.

6 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the Fentanyl Assay, refer to the package insert for the ARK Fentanyl 0.5 ng/mL Assay.
- Calibrators are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume (~40µL/drop) into individual sample cups for each level. Consult instrument-specific sample volume requirements. Return caps to their original containers and keep tight.
- Store at 2-8°C. Use prior to the expiration date.

7 PROCEDURE

Qualitative Results

Use the 0.5 ng/mL Calibrator as a Cutoff Calibrator to distinguish negative and positive samples. Run the Low and High Controls as Negative and Positive respectively. Report test results less than the absorbance (ΔA) value for the Cutoff Calibrator as Negative. Report results equal to or greater than the absorbance (ΔA) value for the Cutoff Calibrator as Positive.

When to Re-Calibrate

- Whenever a new lot number of reagents is used
- Whenever indicated by quality control results
- Whenever required by standard laboratory protocols

8 LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, controls, storage of product as directed, and good laboratory technique.

9 TRADEMARKS

ARK™ is a trademark of ARK Diagnostics, Inc.

Other brand or product names are trademarks of their respective holders.

Negative Kit REF 5052-0002-01

Cutoff Kit REF 5052-0002-02

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